SHARE

NHS SCOTLAND

Participant Information Leaflet

What is SHARE?

SHARE - The Scottish Health Research Register - is a register of adults and children aged 11 and over who are willing to be invited to take part in medical research projects and have also consented to allow researchers to use any left-over blood following routine clinical testing for approved research. Often people who want to be involved in medical research (whether they are unwell or not) don’t know where to start or who to ask. Researchers have a similar problem; they want to do studies but sometimes cannot find people to take part in them.

Getting involved in research studies can range from answering surveys, to having your blood tested, to testing new medical devices and phone apps, and sometimes even participating in clinical trials. With your help, we can help researchers understand diseases better, and find new ways to prevent or treat illnesses and therefore improve future care. SHARE is for both healthy people and those with medical conditions.

When you register, you will also be invited to give permission for any spare blood left-over following routine clinical tests to be kept and used by researchers, for example, looking at the role of genes in diseases. The blood is stored carefully and only used for research that has been ethically approved and you will not be identified so the researchers won’t know whose blood they are using.

Why is SHARE needed?

In order to develop new tests or treatments or ways to improve care, volunteers are needed to take part in research. People who are interested in research do not always know how to find out about it, or how they can get involved. It is also often difficult for researchers to find people who would be willing to take part in research.

We want to make it easier for all people, both healthy and those who may have medical conditions, to become involved by making it easier for researchers to find people interested in participating in research studies and for people to make their interest known. SHARE allows individuals to register their interest directly.

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How does SHARE work and how could I be invited to participate in studies?

Joining the register is easy; all you need to do is provide your name, date of birth, postcode and contact details. This is the only information required to link to your health records within the NHS. Your details will be held securely within the NHS.

1. **You complete the SHARE Registration. Your details will be kept secure within the NHS Systems at the Health Informatics Centre (HIC).**
2. **Researchers will approach SHARE with a prospective project, HIC will carry-out a coded data search to find anyone in SHARE who is eligible. This list of names will be sent to SHARE.**
3. **Only HIC and the SHARE team will be able to see your name and contact details, and they will contact you to explain what the research is about, and to answer questions you may have.**
4. **If you are interested, and only with your agreement, the SHARE team will pass your contact details to the researcher who will get in touch with you to discuss it further.**
5. **You decide if you want to take part. It is your choice and you can say no. There is no obligation to take part in any project. Financial incentives may be available for some studies and others will cover expenses.**
6. **SHARE won't be involved directly in any study you participate in. But we'll keep track of your participation in a study and when the study completes we may contact you about further studies.**

How will my information be used?

Information about your health is stored in various NHS computer records so doctors and other health professionals have the information they need to look after you.

When you register for SHARE, you are giving permission for HIC to search your NHS health information to see if your characteristics match those of people that researchers are looking for to participate in studies. This may include your genetic profile if you have given permission for your blood to be stored. For example, a search might be conducted to find people on the register who are over the age of 40 and have diabetes. The list will be used by the SHARE team to contact the individuals identified to check if they are interested in speaking to the researchers to learn more about getting involved with a particular study.

Researchers will not be able to identify or contact you until you have given permission to the SHARE team for this to happen. Your full medical or genetic record will never be seen by SHARE or the research team, only the parts relevant to the study will be looked at. For example, you may have asthma and diabetes; but if the search was to find people with diabetes, it would not be revealed that you also have asthma. Some people approached by SHARE may not have the condition under exploration and are invited as a ‘control’ participant.

Your privacy is extremely important to the NHS and SHARE and your health information will only be used by SHARE in the way that you have given permission for when registering and in accordance with UK Data Protection Law.

What if I’ve given permission for my blood to be used for research?

Every time you give blood for a routine clinical test, a small amount is left in the tube. This left-over blood can be valuable for research but your permission is needed to keep and use any of this sample. If you have given permission for your spare blood to be collected, no further action is required on your part. You do not need to come to the hospital, and no additional blood samples will be needed. Only spare blood that remains in the NHS laboratory after you have had a test requested by your doctor will be stored. These samples will be stored carefully and coded (de-identified) so they cannot be directly traced back to you as the donor. The samples will only be used in research studies that have been ethically approved and any samples used in research will have all personal information removed so that they cannot be identified as you.

Why do you want my blood for research?

Using your blood researchers can look at, for example, the role of genes in health and disease or to develop new tests to spot disease earlier.

By joining SHARE you are giving permission for your surplus blood to be accessed and securely stored. You are also giving permission for this material to be used for approved research studies that may include genetic analysis and information to be combined with your coded medical data. When your information is used in this way, your privacy is protected and personal details which identify you are removed (the information is ‘de-identified’). For example, if researchers are looking for blood from asthma patients to study the genes involved in asthma then they will get samples (after approval) from these patients (with no identifiers) but with knowledge that the samples came from asthma patients.

Will you take blood from me?

It is only blood left-over from samples you may give in the future for testing when you visit your doctor or hospital that will be used. You are simply giving permission for researchers to use any of the left-over blood following routine clinical testing. No more blood will be taken than is usual for standard medical tests. You will not have to give extra samples.

What will happen to my blood sample?

Any blood collected will be carefully and securely stored indefinitely for future research. Multiple samples from you might be kept. These will be used when the original sample runs out, but they might also be used to look at changes in molecules in your blood over time. For example, researchers might look at how molecules in the blood change during the course of a disease, or during treatments.

Samples of your blood may also be sent to other research groups, including outside the UK. As before, the sample will be de-identified so that you cannot be identified. The transfer of samples will be strictly controlled to ensure your privacy is protected and it is only used in ethically approved research studies, which could be funded by the public, charity or pharmaceutical sector organisations.

Who will look after my donated blood samples?

Blood samples that are collected will be looked after by special facilities within the NHS called human tissue biorepositories. There are four of these in Scotland and they all have been independently accredited to ensure that they follow best practice and relevant laws around the collection, storage and use of human tissue samples. They make sure that the blood samples are coded (de-identified), stored carefully and safely, and that they are only given to researchers for ethically approved research studies. More information about these biorepositories is at: **https://www.nhsresearchscotland.org.uk/research-in-scotland/facilities/biorepositories-and-tissue-services**

What kind of research will be done on the sample I give permission for?

Recent advances in early diagnosis and treatment of diseases have been in part due to understanding genes and how people's genetic code can influence disease and their responses to medications. This is an important growing area of research as the discovery of genetic variations can be used to develop new, more effective diagnostic tests, and drug treatments that can be better tailored to patients.

Many people in Scotland have already been involved in genetic studies. 10% of the Scottish population has already volunteered for genetic studies into diabetes, obesity, cancer, heart disease, asthma, COPD, eczema or heart disease.

SHARE is helping expand the valuable research being carried out in these and other disease areas. You are giving consent for samples to be used for genetic research; this may eventually involve the reading of your entire genome (all 3 billion letters of your genetic code). In this way, information gathered may provide useful guidance for the development of new tests or treatments. You may be selected and invited for research studies based on your genetic information in the future.

Your samples will also be used to study changes in molecules in your blood over time. For example, researchers might look at how molecules in the blood change during the course of a disease, or during treatments. Several samples may be retained over the course of your disease or particular treatment.

What happens when new information is found from this research?

Medical researchers are at an early stage of understanding the importance of most of your genetic code and what differences in the code between people may mean. Researchers using your blood samples will produce reports and publications of what they find out, and that information could point to a better understanding of how diseases develop or new ways to treat illnesses. However, because researchers don't know whose blood they are using you won't be identified in these reports and publications and they or SHARE will not provide information to you about your own individual results.

Nevertheless, as knowledge improves, including from research supported by SHARE, this could guide future tests and treatments offered by the NHS.

It is also possible that information about you that comes from research on your samples could be important and helpful to doctors treating you in the future. If that is the case, it may be appropriate at some point in the future for this information to be added to your medical records. For example, we know that people respond differently to some drugs given to prevent heart disease depending on their genetic code. However, SHARE is not set up to do this currently and a change to this policy will require further ethical review and your consent.

What if I change my mind after registration?

If you no longer wish to be contacted for research you simply need to contact us by email or telephone and we will arrange for your details to be removed from the register. Similarly, if you no longer wish your blood samples to be used in research we will ask for any samples held under the control of the biorepositories to be destroyed. You can withdraw from SHARE at any time in the future, and you do not need to give a reason.

What are the benefits of taking part in SHARE?

SHARE is making it easier to carry out health research in Scotland. This research is essential to learn about people's health and find better ways to treat and prevent disease. The more people get involved in research the better the help research can be to improving the future health of the whole population.

You can keep up to date with research taking place on the SHARE website and our e-newsletters.

Will my taking part in this project be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Patient confidentiality is paramount within the NHS and SHARE. Your full medical record will never be seen.

How long will I be registered for?

This register does not have a defined end date. We will keep you on the SHARE register indefinitely and if you have given permission for use of your blood this too may be kept indefinitely. However, you are free to end your involvement at any time. Just contact the SHARE Team.

Do I need to declare my involvement for Medical Insurance?

Your agreement is to be registered to SHARE and, if you have given permission, to have blood stored for research, and not for the purposes of your medical care. Therefore insurance companies do not need to be informed.

Will I be paid for taking part?

No, you will not be paid for joining the SHARE register, or for allowing your spare blood to be used in research studies.

Who is organising and funding SHARE?

The SHARE register is part of NHS Research Scotland and is organised and sponsored by NHS Tayside with funding from the Scottish Government Chief Scientist Office. The collection, storage and approved access of spare blood is organised and sponsored by the University of Dundee in collaboration with the Universities of Edinburgh, Aberdeen and Glasgow with funding from the Wellcome Trust and Pharmaceutical companies.

Who has reviewed SHARE?

The South East Scotland Research Ethics Committee 02 has examined the proposal and has raised no objections from the point of medical ethics. The blood collection has also been reviewed by members of the scientific review board of the Wellcome Trust.

Glossary of terms;

Anonymous Data: This is information where an individual cannot be identified. This can be when data has had all identifiable elements removed, or when data from many people is combined (presented often as statistics).

De-identified information: This is information that does not identify an individual, because identifiers have been removed or encrypted. However, the information is still about an individual person and so needs to be handled with care. It might, in theory, be possible to re-identify the individual if the data was not adequately protected, for example if it was combined with different sources of information.

Personal Data/Personally Identifiable/Confidential Information: This is information that identifies a specific person. Identifiers include: name, address, geographic locators, date of birth or national health number.

For more information on the above, please see Identifiability Demystified: **https://understandingpatientdata.org.uk/sites/default/files/2017-04/Identifiability%20briefing%205%20April.pdf**

If you have any questions or wish to register by telephone please call the **SHARE Team** on **01382 383230** or **01382 383471**

Alternatively, you may contact us by email **enquiries@registerforshare.org**

Many thanks for taking the time to read this information.

www.registerforshare.org